As January 14, 1995 falls on a Saturday and Monday is Martin Luther King Jr. Day (a holiday in the Patent Office), the Response is due on January 17, 1995.

Applicants respectfully request that the following submissions be entered.

IN THE ABSTRACT

No changes.

IN THE DISCLOSURE

No changes.

IN THE CLAIMS

6. (Twice Amended) A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which comprises administering topically to the mammal a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective

(to treat and resolve the disease, condition or lesion), non-toxic (to the patient) dosage amount of a drug which inhibits prostaglandin synthesis (component (1)) and an effective dosage amount comprising at least 50-60 mg of hyaluronic acid and/or pharmaceutically acceptable salts thereof and/or [homologues, analogues, derivatives, complexes, esters,] fragments, and/or sub-units [of hyaluronic acid] thereof (component (2)) sufficient to transport (facilitate the transport of) the drug (component (1)) into the skin and/or exposed tissue (including any scar tissue) at the site of the disease or condition to be treated to block prostaglandin synthesis.

8. (Twice Amended) The method of Claim 6 wherein the hyaluronic acid and/or pharmaceutically acceptable salts thereof and/or [homologues, analogues, derivatives, complexes, esters,] fragments, and/or sub-units [of hyaluronic acid] thereof is hyaluronic acid or a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons.

10. (Twice Amended) The method of Claim 9 wherein the NSAID is selected from diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, aceytylsalicylic acid and Flunixin.

11. (Thrice Amended) The method of Claim 9 wherein [the amount of the hyaluronic acid or salt thereof is in excess of 50-60 mg per dosage and has a molecular weight less than about 750,000 daltons.]

(i) the concentration of component (2) equals or exceeds a concentration of 1 1/2% by weight of the dosage amount;

(ii) the concentration of component (1) equals or exceeds a concentration of 1% by weight of the dosage amount;

(iii) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or exceeds 1% by weight of the dosage amount;

(iv) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount;

(v) component (2) equals or is less than 3% by weight of the dosage amount and component (1) equals or exceeds 1% by weight of the dosage amount;

(vi) component (2) equals or exceeds 1 1/2% by weight of the dosage amount and component (1) equals or exceeds 1% by weight but is less than or equal to 5% by weight of the dosage amount;

(vii) component (2) equals or is less than 3% by weight of the dosage amount and component (1) equals or exceeds 1% by weight but is less than or equal to 5% by weight of the dosage amount;

(viii) component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component 1) equals or exceeds 1% by weight of the dosage amount;

(ix) component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight or the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount; and

(x) component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

12. (Twice Amended) The method of Claim [7] 11 wherein [the hyaluronic acid and/or pharmaceutically acceptable salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid is hyaluronic acid or a salt thereof.] component (2) is sodium hyaluronate having a molecular

weight less than about 750,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

13. (Amended) The method of Claim [12] 11 wherein [the drug is a non-steroidal anti-inflammatory drug (NSAID).] the concentration of component (1) is set out in subparagraph (ii).

14. (Twice Amended) The method of Claim [13] 11 wherein [the NSAID is selected from diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.] the concentration of components (1) and (2) are those set out in subparagraph (iii).

15. (Thrice Amended) The method of Claim [13] 11 wherein [the amount of the hyaluronic acid or salt thereof is in excess of 50-60 mg per dosage and has a molecular weight less than about 750,000 daltons.] the concentration of components (1) and (2) are those set out in subparagraph (iv).

16. (Amended) The method of Claim 11 wherein [Transdermal delivery of a therapeutically effective amount of a drug which prohibits prostaglandin synthesis applied topically to treat a disease or condition of the skin and exposed tissue comprising basal cell carcinoma,] the [precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin,

genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal, the delivery comprising administering in a pharmaceutically acceptable form, topically a therapeutically effective (to treat the disease or condition of the skin or exposed tissue) non-toxic (to the patient) dosage amount of such drug and an effective dosage amount of hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and sub-units of hyaluronic acid sufficient to transport, (facilitate the transport of), the drug to the site of the disease or condition to block prostaglandin synthesis.] concentration of components (1) and (2) are those set out in subparagraph (v).

17. (Amended) The [delivery] method of Claim [16] 11 wherein [the hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and sub-units of hyaluronic acid, preferably hyaluronic acid and/or pharmaceutically acceptable salts thereof is selected from hyaluronic acid and/or pharmaceutically acceptable salts thereof.] the concentration of components (1) and (2) are those set out in subparagraph (vi).

18. (Amended) The [delivery] method of Claim [17] 11 wherein [the drug is a non-steroidal anti-inflammatory agent (NSAID).] the concentration of components (1) and (2) are those set out in subparagraph (vii).

19. (Twice Amended) The [delivery] method of Claim [18] 11 wherein [the NSAID is selected from diclofenac, indomethacin,

naproxen, and (+/-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, aceytylsalicylic acid and Flunixin.] the concentration of components (1) and (2) are those set out in subparagraph (viii).

20. (Twice Amended) The [delivery] of Claim [18] 11 wherein [the amount of the hyaluronic acid or salt thereof is in excess of 50-60 mg per dosage and has a molecular weight less than about 750,000 daltons.] the concentration of components (1) and (2) are those set out in subparagraph (ix).

Please add new Claim 26 as follows:

26. The method of Claim 11 wherein the concentration of components (1) and (2) are those set out in subparagraph (x).

The fee of $22.00 for adding this dependent claim is enclosed. If insufficient funds have been provided, please debit Account #08-3255 for the necessary additional funds. If excess funds have been submitted, please credit Account #08-3255 with the excess.

Remarks

Of the Claims being examined by Examiner Martin, Claims 6 to 20 inclusive and Claim 26 remain in the case to be examined. No new subject matter was added by the amendments made to the Claims above. Particularly, all of the subject matter has been described. Having regard to Claims 11 to 20, and 26, the subject matter thereof (namely concentrations) is disclosed in the Formulations 1 to 9 described at